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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/601,940	06/23/2003	Robert E. Sosnowski	1107-3 DIV	7862

7590 07/13/2006

Gerald T. Bodner
Bodner & O'Rourke, LLP
425 Broadhollow Road, Suite 108
Melville, NY 11747

EXAMINER	
COTTON, ABIGAIL MANDA	

ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 07/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/601,940	SOSNOWSKI ET AL.	
	Examiner	Art Unit	
	Abigail M. Cotton	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *6/23/03,10/8/03,11/23/04 and 5/8/06*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *7-29* is/are pending in the application.

4a) Of the above claim(s) *13-29* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *7-12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *10/8/2003*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 7-29 are pending in the application, with claims 13-29 withdrawn as drawn to a non-elected invention. Accordingly, claims 7-12 are being examined on the merits herein.

Election/Restrictions

Applicant's election of the claims of Group I, namely claims 7-12, in the reply filed on May 8, 2006 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Furthermore, the Examiner notes that, as discussed in the restriction requirement mailed on April 7, 2006, Groups I-IV are drawn to different compositions and methods of treating diverse conditions, and thus represent patentably distinct inventions that would pose an undue search burden should all or even just two of the inventions be required to be searched at the same time, as the inventions require searching not only for novelty and non-obviousness, but also for the enablement of the claimed methods of treatment and intended uses of the claimed compositions.

The restriction requirement is deemed proper and is made final. Claims 13-29 are being withdrawn as drawn to a non-elected invention.

Priority

Applicant's claim of domestic priority as a divisional of U.S. Patent Application Serial No. 09/845,141, filed April 30, 2001, now U.S. Patent No. 6,583,152, is acknowledged.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 7-12 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for lowering homocysteine levels in the body with the claimed compositions, does not reasonably provide enablement for the *reducing the risk of*, i.e. preventing cardiovascular disease with the composition as claimed. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The instant specification fails to provide information that would allow the skilled artisan to fully practice the instant invention without ***undue experimentation***. Attention

is directed to *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Foreman*, 230 USPQ 546 (Board of Appeals 1986) at 547, the court recited eight factors:

(1) the nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art: (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation that is necessary.

(1) *The Nature of the Invention:*

The invention is drawn to a composition that is for *reducing the risk* or progression of cardiovascular disease with a composition consisting essentially of dextromethorphan, folic acid or folate, vitamin B6 and Vitamin B12, as well as embodiments having further ingredients. The recitation that the composition is for "reducing the risk" of cardiovascular disease, absent any showing to the contrary, is considered to include reducing the risk to the point that cardiovascular disease is prevented.

(2) ***Breadth of the Claims:***

The complex nature of the subject matter of this invention is greatly exacerbated by the breadth of the claims. The claimed invention includes reducing the risk, i.e. preventing cardiovascular disease by lowering homocysteine levels in the body with the composition. The phrase "lowering the risk of" indicates a claim whereby even those normally not at risk for developing such a disorder would be prevented from ever developing the cardiovascular disease with the composition.

(3) ***Guidance of the Specification:***

The guidance of the specification as "lowering the risk of" or "preventing" cardiovascular disease is completely lacking. The specification does not provide any experimental results indicating prevention or lowering the risk of cardiovascular disease, and instead teaches that components of the composition are known in the art to reduce homocysteine levels, which Applicants' indicate is related to the development of cardiovascular diseases (see column 1, lines 5-65, in particular.) Applicants do not show any results that demonstrate the actual lowering of risk or prevention of cardiovascular disease, and do not posit any model by which potential prevention of lowering of risk could be determined. Thus, the specification does not provide any information regarding the lowering of risk and/or complete *prevention* of cardiovascular

disease in a population, as would be required by a claim for prevention or lowering of risk for a condition.

(4) *Working Examples:*

As discussed in the Guidance of the Specification section above, Applicant have not shown any working examples that demonstrate the lowering of risk and/or prevention of cardiovascular disease.

(5) *State of the Art:*

The state of the art regarding the *treatment* of cardiovascular disease is well developed. However, the state of the art regarding the *reduction in risk* or *prevention* of cardiovascular disease is underdeveloped (see for example U.S. Patent No. 6,054,128 to Diane Wakat, issued Aril 25, 2000.) Wakat describes how the degree to which an individual is affected by cardiovascular disease such as atherosclerosis is dependent upon a number of factors including age, gender, genetics and various life-style choices, including diet (see column 1, lines 10-28, in particular.) Thus, Wakat teaches that a number of factors are correlated with the development of cardiovascular disease, but the exact relationship amongst the correlative factors is unknown.

Reasonable guidance with respect to *reducing the risk of* or *preventing* cardiovascular disease relies on quantitative analysis from defined populations that have been successfully pre-screened and are predisposed to cardiovascular disease. This type of data might be derived from widespread genetic analysis, family histories, correlation of genetic and environmental factors, etc. The essential element towards the validation of a preventive therapeutic is the ability to test the drug on subjects monitored in advance of cardiovascular disease onset, and *link* those results with subsequent histological confirmation of the presence or absence of cardiovascular disease. This irrefutable link between antecedent drug and subsequent knowledge of the prevention of the disease is the essence of a valid preventive agent. As the correlation among factors contributing to cardiovascular disease is not known, the state of the art does not provide a reasonable method of making such a predictive analysis. Further, a preventive administration also must assume that the therapeutic will be safe and tolerable for anyone susceptible to the disease.

(6) *Predictability of the Art*

The invention is directed to the *reducing the risk of,* i.e. *preventing* cardiovascular disease *in general* with the claimed compound. It is well established that "the scope of enablement varies inversely with the degree of unpredictability of the factors involved," and physiological activity is generally considered to be an unpredictable factor. See *in re Fisher*, 427 F.2d 833, 839 (1970.)

It should also be noted that one of ordinary skill in the art would recognize that it is highly unpredictable in regard to what population will experience a cardiovascular disease and to what extent, as discussed in (5) above. In order to administer the agent to the population at large, one would need to consider the therapeutic effects, side effects and especially potential serious toxicity that may be generated by drug-drug interactions as a result of administration of the claimed compounds to a living organism (e.g., an animal.)

(7) ***The Quantity of Experimentation Necessary:***

In order to practice the disclosed invention, one would need to undergo experimentation to test the claimed compositions to determine whether or not any of they are capable of reducing the risk of and/or completely preventing cardiovascular disease, as the instant specification does not show the complete prevention thereof.

As discussed above, the specification fails to provide sufficient support for determining all individuals susceptible to cardiovascular disease and to what extent to allow one or ordinary skill in the art to administer to a population the composition of the instant invention for the *prevention* or *lowering of risk* of cardiovascular disease in general. As a result, one of ordinary skill in the art would be forced to perform an

exhaustive search for the population that is susceptible to a certain extent of cardiovascular disease to use the instant invention.

Genentech, 108 F.3d at 1366 states that "a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion" and "[p]atent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable."

The Examiner suggests deleting the reference to "reducing the risk" in the claims. For examination purposes, the Examiner is interpreting the claims as drawn to a composition that is for reducing the progression of cardiovascular disease.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,054,128 to Diane Wakat, issued April 25, 2000, in view of U.S. Patent No. 6,025,369 to Rosenquist et al.

Wakat teaches dietary supplements for the cardiovascular system (see abstract, in particular.) Wakat teaches that it is known that Vitamin B_{12}, Vitamin B_6 and folic acid reduce serum levels of homocysteine, high levels of which are associated with coronary heart disease (see column 4, lines 50-60, in particular.) Wakat also teaches that antioxidants such as vitamin E and beta-carotene can reduce the risk of cardiovascular disease, and can protect arterial walls as well as lower LD cholesterol levels (see column 4, lines 14-35, in particular.) Wakat further teaches that botanical compounds such as phytochemicals and bioflavanoids improve cardiac function (see column 5, lines 22-50, in particular), and that procyanidin or cyanidin protect vascular endothelial cells (see column 5, lines 50-60, in particular.) Thus, Wakat teaches that dietary supplements such as folic acid, vitamin B6, vitamin B12, vitamin E, beta-carotene, procyanidins and flavanoids, contribute to cardiovascular health, and thus can be provided in a method of reducing the progression of cardiovascular disease, as recited in claim 7.

Wakat does not specifically teach dextromethorphan, as recited in the claim 7.

Rosenquist et al. teaches that NMDA receptor antagonists can be used to treat and prevent atherosclerosis, which is the principle cause of cardiovascular disease (see abstract and column 1, lines 28-45, in particular.) Rosenquist et al. teaches that examples of suitable NMDA receptor antagonists include dextromethorphan, which is

an orally available drug (see column 10, lines 30-50, and column 13, lines 5-35, in particular.)

Accordingly, one of ordinary skill in the art at the time the invention was made would have found it obvious to combine the dextromethorphan of Rosenquist et al. with the folic acid, vitamin B_6, vitamin B_{12}, vitamin E, beta-carotene and flavanoids/procyanidins of Wakat to provide a composition for reducing the risk of cardiovascular disease, because Wakat teaches that each of the individual ingredients promotes and protects cardiovascular health, while Rosenquist et al. teaches that dextromethorphan prevents or treats atherosclerosis, which is a primary cause of cardiovascular disease. Thus, one of ordinary skill in the art would have been motivated to combine the ingredients into a single composition with the expectation of providing a composition capable of promoting cardiovascular health, and would have been motivated to administer the composition to a person in need of the reduction of the progression of cardiovascular disease. Note it is considered that "[I]t is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art." In re Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980.)

Claims 8-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,054,128 to Diane Wakat, issued April 25, 2000, in view of U.S. Patent No. 6,025,369 to Rosenquist et al, issued February 15, 2000, as applied to claim 7 above, and further in view of U.S. Patent No. 5,028,449 to Hiroji H. Hatanaka, issued July 2, 1991.

Wakat and Rosenquist et al. are applied as discussed for claim 7 above, and teach that teach that dietary supplements can be provided to promote the health of the cardiovascular system and reduce the progression of cardiovascular disease. Rosenquist et al. teaches that it is known that dextromethorphan promotes cardiovascular health, whereas Wakat teaches that it is known that Vitamin B_{12}, Vitamin B_6 and folic acid reduce serum levels of homocysteine, high levels of which are associated with coronary heart disease (see column 4, lines 50-60, in particular.) Wakat also teaches that antioxidants such as vitamin E and beta-carotene can reduce the risk of cardiovascular disease, and can protect arterial walls as well as lower LD cholesterol levels (see column 4, lines 14-35, in particular.) Wakat further teaches that botanical compounds such as phytochemicals and bioflavanoids improve cardiac function (see column 5, lines 22-50, in particular), and that procyanidin or cyanidin protect vascular endothelial cells (see column 5, lines 50-60, in particular.) Thus, Wakat teaches that dietary supplements such as folic acid, vitamin B6, vitamin B12, vitamin E, beta-carotene, procyanidins and flavanoids, as recited in claims 8-10, can be provided to contribute to cardiovascular health.

Wakat and Rosenquist et al. do not specifically teach providing lecithin as a part of the composition for the treatment of and/or to reduce the progression of cardiovascular disease.

Hatanaka teaches a product from egg oil (lecithin), and teaches that lecithin is known to be a useful treatment for heart ailments and for the improvement and/or prevention of arteriosclerosis and hypertension (see abstract and column 1, lines 5-65, in particular.) Hatanaka also teaches that lecithin can be provided as a dietary supplement (see paragraph bridging columns 3-4, in particular.) Thus, Hatanaka teaches that lecithin can be provided to promote cardiovascular health.

Accordingly, one of ordinary skill in the art at the time the invention was made would have found it obvious to combine the lecithin of Hatanaka with the folic acid, vitamin B_6, vitamin B_{12}, vitamin E, beta-carotene, flavanoids/procyanidins and dextromethorphan of Wakat and Rosenquist et al, to form a composition having the ingredients, and to provide the composition to a person in need of the reduction of the progression of cardiovascular disease, because Wakat and Rosenquist et al. teach that each of the individual ingredients promotes and protects cardiovascular health, while Hatanaka teaches that lecithin promotes cardiovascular health by preventing arteriosclerosis and treating heart ailments. Thus, one of ordinary skill in the art would have been motivated to combine the ingredients into a single composition, and

providing to a patient in need thereof, with the expectation of providing a composition capable of promoting cardiovascular health. Note it is considered that "[I]t is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art." In re Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980.)

Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,054,128 to Diane Wakat, issued April 25, 2000, in view of U.S. Patent No. 6,025,369 to Rosenquist et al, issued February 15, 2000, and further in view of U.S. Patent No. 5,028,449 to Hiroji H. Hatanaka, issued July 2, 1991, and further in view of the article entitled "Plasma Homocyst(e)ine: A Risk Factor for Arterial Occlusive Diseases" by M.R. Malinow, 1996, the Journal of Nutrition, 124 42, pages 1238S-1243S, and U.S. Patent No. 6,030,621 to De Long et al, issued February 29, 2000.

Wakat, Rosenquist et al. and Hatanaka are applied as discussed above, and teach a composition comprising dextromethorphan, folic acid, vitamin B_6, vitamin B_{12}, lecithin, vitamin E, beta-carotene and a procyanidin/flavanoid, that promotes cardiovascular health.

Wakat, Rosenquist et al. and Hatanaka do not specifically teach the composition comprising trimethylglycine or ginkgo biloba, as recited in the claim.

Malinow teaches the plasma homocysteine concentrations are a risk factor in coronary arterial occlusive diseases, and can be decreased by supplements such as folate or folic acid that can be provided with betaine (trimethylglycine) (see abstract and page 1242S, in particular.) Thus, Malinow teaches that trimethylglycine can be provided to reduce the risk of coronary arterial occlusive diseases, and especially in combination with folate or folic acid, and thus teaches promoting cardiovascular health with the administration of the trimethylglycine.

Accordingly, one of ordinary skill in the art at the time the invention was made would have found it obvious to combine the trimethylglycine of Malinow with the folic acid, vitamin B_6, vitamin B_{12}, vitamin E, beta-carotene, flavanoids/procyanidins, dextromethorphan and lecithin of Wakat, Rosenquist et al. and Hatanaka, to form a composition having the ingredients, and to provide to a person in need of the reduction of the progression of cardiovascular disease, because Wakat, Rosenquist et al. and Hatanaka teach that each of the individual ingredients promotes and protects cardiovascular health, while Malinow teaches that trimethylglycine (betaine) reduces homocysteine levels, which are a risk fact for coronary arterial occlusive disease, and particularly in combination with folic acid or folate, such as is taught by Wakat. Thus, one of ordinary skill in the art would have been motivated to combine the ingredients

into a single composition and provide to a person in need thereof with the expectation of providing a composition capable of promoting cardiovascular health. Note it is considered that "[I]t is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art." In re Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980.)

Wakat, Rosenquist et al, Hatanaka and Malinow do not specifically teach that the composition comprises ginkgo biloba, as recited in the claim.

De Long et al. teaches a composition comprising an extract from ginkgo biloba (see abstract, in particular.) De Long et al. teaches that compounds in gingko biloba have been found to treat and/or inhibit disorders such as cardiac disorders and other circulatory system diseases (see column 1, lines 60-65, in particular.) Thus, De Long et al. teaches that ginkgo biloba can be provided in a composition to treat and/or inhibit cardiovascular disorders.

Accordingly, one of ordinary skill in the art at the time the invention was made would have found it obvious to combine the ginkgo biloba of De Long et al. with the folic acid, vitamin B_6, vitamin B_{12}, vitamin E, beta-carotene, flavanoids/procyanidins, dextromethorphan, lecithin and trimethylglycine of Wakat, Rosenquist et al, Hatanaka

and Malinow, to form a composition having the ingredients, and to provide to a person in need of reducing the progression of cardiovascular disease, because Wakat, Rosenquist et al, Hatanaka and Malinow teach that each of the individual ingredients promotes and protects cardiovascular health, while De Long et al. teaches that ginkgo biloba treats and/or inhibits cardiac disorders, and thus promotes the health of the cardiovascular system. Thus, one of ordinary skill in the art would have been motivated to combine the ingredients into a single composition and provide to a person in need thereof with the expectation of providing a composition capable of promoting cardiovascular health. Note it is considered that "[I]t is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art." In re Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980.)

Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,054,128 to Diane Wakat, issued April 25, 2000, in view of U.S. Patent No. 6,025,369 to Rosenquist et al, issued February 15, 2000, U.S. Patent No. 5,028,449 to Hiroji H. Hatanaka, issued July 2, 1991, the article entitled "Plasma Homocyst(e)ine: A Risk Factor for Arterial Occlusive Diseases" by M.R. Malinow, 1996, the Journal of Nutrition, 124 42, pages 1238S-1243S, and U.S. Patent No. 6,030,621 to De Long et al, issued February 29, 2000, and further in view of U.S. Patent No. 5,605,927 to Ruth Korth, issued February 25, 1997.

Wakat, Rosenquist et al, Hatanaka, Malinow and De Long et al. are applied as discussed for claims 4-5 above, and teach a composition that promotes cardiovascular health comprising dextromethorphan, folic acid or folate, vitamin B_6, vitamin B_{12}, lecithin, vitamin E, beta-carotene, a procyanidin/flavanoid, trimethylglycine and gingko biloba.

It is furthermore noted that Wakat teaches that dietary supplements of trace elements (minerals) such as selenium, zinc, chromium, magnesium and copper have potential benefit in cardiovascular diseases (see column 1, lines 40-65, in particular.)

The references do not specifically teach providing garlic oil in the composition.

Korth teaches that garlic oils are commercially available for the treatment of hyperlipidemic as well as cardiovascular diseases (see column 5, lines 40-45, in particular.)

Accordingly, one of ordinary skill in the art at the time the invention was made would have found it obvious to combine the minerals of Wakat and the garlic oil of Korth with the folic acid, vitamin B_6, vitamin B_{12}, vitamin E, beta-carotene, flavanoids/procyanidins, dextromethorphan, lecithin and trimethylglycine of Wakat, Rosenquist et al, Hatanaka, Malinow and De Long et al, to form a composition having the ingredients, and to provide to a person in need of reducing the progression of

cardiovascular disease, because Wakat, Rosenquist et al, Hatanaka, Malinow and De Long et al. teach that each of the individual ingredients promotes and protects cardiovascular health, while Wakat teaches that minerals treat or prevent cardiovascular diseases, and Korth teaches that garlic oil is commercially available for the treatment of cardiovascular diseases. Thus, one of ordinary skill in the art would have been motivated to combine the ingredients into a single composition, and providing to a person in need thereof, with the expectation of providing a composition capable of promoting cardiovascular health. Note it is considered that "[I]t is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art." In re Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980.)

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 7-12 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-6 and 30-31 of copending Application No. 10/601,942. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the conflicting application are to a composition that is "for reducing the risk or progression of cardiovascular disease by lowering homocysteine levels in the body" that has the same ingredients (i.e. dextromethorphan, folic acid or folate, vitamin B6 and vitamin B12, etc) as those in the instant claim, whereas the instant claims are to a method of reducing the

risk or progression of cardiovascular disease with the composition. Accordingly, as the conflicting claims in the 10/601,942 application recite that the composition is useful for reducing the progression of cardiovascular disease, it is considered that one of ordinary skill in the art would find it obvious to use the composition in the method of treatment as in the instant claims. Accordingly, claims 7-12 are unpatentable over claims 1-6 and 30-31 of copending Application No. 10/601,942.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

No claims are allowed.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. WO 00/25764 to Buchholz et al. teaches a composition for treating cardiovascular disease comprising bioflavanoids (see abstract, in particular.)

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Abigail M. Cotton whose telephone number is (571) 272-8779. The examiner can normally be reached on 9:30-6:00, M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

AMC

SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER